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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/820,531 | 03/29/2001 | Eugenia Wang | UNLV 1010 | 3924 |

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| EXAMINER | |
|---|---|
| WHISENANT, ETHAN C | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1634 | |

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/820,531 | WANG, EUGENIA | |
| | Examiner | Art Unit | |
| | Ethan Whisenant, Ph.D. | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *21-29 and 34-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-29,34-36 and 38-40* is/are rejected.

7)☒ Claim(s) *37* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## NON-FINAL REJECTION

**1.** The applicant's Response (filed 26 MAR 03) to the Office Action has been entered. Following the entry of the claim amendment(s), **Claim(s) 21-29 and 34-40** is/are pending. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

### 35 USC § 112- 2ND PARAGRAPH

**2.** The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

### CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

**3.** **Claim(s) 21, 26-29, 34-36 and 38-40** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Claims 21 and 34** are indefinite because there is no nexus between the preamble and the claim steps. Claims 21 and 34 in their preambles direct to a method which is to accomplish a particular goal. However, none of the claim steps states that this goal is accomplished. For clarity, claimed methods should recite that the purpose of the method has been attained (i.e. provide a nexus between the preamble and the claim steps). Note that the preamble of Claim 21 recites "detecting changes in the expression of genes", however the claim steps never recites that this purpose of the method has been attained. In order to detect changes one must first have a baseline to compare. For example, at time-point X the expression level of gene Y is Z. Then at time-point X+1 following treatment with drug W, the expression level of gene Y is 2Z. Please amend the claims to make it clear that the claimed methods recite that the purpose of the method has been attained (i.e. provide a nexus between the preamble and the claim steps).

Note that Claim 22 and its dependents, and Claim 37, have not been included in this rejection because there is a comparison step in Claims 22 and 37 wherein the expression in a first library is compared to that in a second library.

**35 USC § 102**

**4.** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) The invention was described in –
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

**35 USC § 103**

**5.** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

### CLAIM REJECTIONS UNDER 35 USC § 102/103

**6.** **Claim(s) 21-29** is/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Heller et al. (1997).

Heller et al. teach a method comprising all of the limitations of Claims 21-29 except these authors do not explicitly teach that the set of primers used to amplify the nucleic acid sequence in the genes in the microarray comprise a non-consensus sequence, rather these authors teach "For closely related genes, targets were designed by avoiding long stretches of homology. For members of a gene family two or more target regions were included to discriminate between specificity of signal versus cross-hybridization." See at least Column 2, page 2152 of Heller et al. Based on this finding, it is argued that the limitation which the applicant asserts is their distinguishing limitation is inherent to the method of Heller et al. In light of this teaching and absent a showing of unexpected results it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to amplify the nucleic acid sequence in the genes in the microarray comprise a non-consensus sequence

### ALLOWABLE SUBJECT MATTER

**7.** **Claim(s) 34-36 and 38-40** would appear to be allowable over the prior art if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph set forth in this Office action.

### CLAIM OBJECTIONS

**8.** **Claim(s) 37** is /are objected to as being dependent upon a rejected base claim, but would appear to be allowable over the prior art of record.

### RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

**9.** Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are moot in view of the new ground(s) of rejection. As regards the applicant's contention that none of the prior art recognizes how one can design the primers to minimize non-specific binding in a

method for screening of a microarray, the examiner points the applicant to at least Column 2, page 2152 of Heller et al. wherein these authors teach "For closely related genes, targets were designed by avoiding long stretches of homology. For members of a gene family two or more target regions were included to discriminate between specificity of signal versus cross-hybridization." See also the prior art rejection set forth above.

**CONCLUSION**

**10.** **Claim(s) 21-29 and 34-40** is/are rejected and/or objected to for the reason(s) set forth above.

**11.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.

**ETHAN WHISENANT**
**PRIMARY EXAMINER**